4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-2048]

Medical Device Epidemiology Network Registry Task Force Report; Availability, Web Site Location and Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the report and Web site location where the Agency has posted the report entitled "Recommendations for a National Medical Device Evaluation System: Strategically Coordinated Registry Networks to Bridge the Clinical Care and Research," developed by the Medical Device Epidemiology Network's Medical Device Registry Task Force. In addition, FDA has established a docket where stakeholders may provide comments.

DATES: Submit either electronic or written comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on this document to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Danica Marinac-Dabic, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4110, Silver Spring, MD 20993-0002, 301-796-6689, email: Danica.marinac-dabic@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA's Center for Devices and Radiological Health is responsible for protecting the public health by assuring the safety and effectiveness of medical devices and radiation-emitting products. A key part of this mission is to monitor medical devices and radiological products for continued safety and effectiveness after they are in use and to help the public get the accurate, science-based information they need to improve their health.

In September 2012, the FDA published a report, "Strengthening Our National System for Medical Device Postmarket Surveillance," that proposed a strategy for improving the current system for monitoring medical device safety and effectiveness. In April 2013, the FDA issued an update to the September 2012 report that incorporated public input received and described the next steps towards fulfilling the vision for building a national postmarket surveillance system. These reports can be found at FDA's Web site http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm301912.htm.

One of these next steps consisted of establishing a multistakeholder Medical Device Registry Task Force to promote the development of national and international device registries for selected products (Ref. 1). Under a cooperative agreement with the FDA, Duke University convened the Medical Device Registry Task Force as a part of the Medical Device Epidemiology

Network public-private partnership in 2014. The Task Force membership included representatives from a broad array of stakeholder groups and areas of expertise including patients, provider organizations, hospitals, health plans, industry, government agencies, as well as methodologists and academic researchers.

The Medical Device Registry Task Force was charged to: (1) Identify existing registries that may contribute to the system; (2) leverage ongoing registry efforts focused on quality improvement, reimbursement, patient-centered outcomes and other activities to best meet the needs of multiple stakeholders; (3) identify priority medical device types for which the establishment of a longitudinal registry is of significant public health importance; (4) define registry governance and data quality practices that promote rigorous design, conduct, analysis, and transparency to meet stakeholder needs; and (5) develop strategies for the use of registries to support premarket approval and clearance (Ref. 1).

This notice announces the availability and Web site location of the Medical Device Registry Task Force's report, entitled "Recommendations for a National Medical Device Evaluation System: Strategically Coordinated Registry Networks to Bridge the Clinical Care and Research." FDA invites interested persons to submit comments on this report. We have established a docket where comments may be submitted (see ADDRESSES). We believe this docket is an important tool for receiving feedback on this report from interested parties and for sharing this information with the public. To access "Recommendations for a National Medical Device Evaluation System: Strategically Coordinated Registry Networks to Bridge the Clinical Care and Research" report, visit FDA's Web site http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm301912.htm.

II. Request for Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

III. Reference

The following reference has been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. We have verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document publishes in the Federal Register.

1. "Strengthening Our National System for Medical Device Postmarket Surveillance: Update and Next Steps," April 2013, available at http://www.fda.gov/downloads/MedicalDevices/Safety/CDRHPostmarketSurveillance/UCM348845.pdf.

Dated: August 19, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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